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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,330	01/23/2004	Michael P. Cooke	P1097US10	5772

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPLegal@gnf.org
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Office Action Summary	Application No.	Applicant(s)	
	10/764,330	COOKE ET AL.	
	Examiner	Art Unit	
	AMY E. JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14-16,28-32 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14-16, 28-32, and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 4/4/08 are acknowledged.

Claims 12, 30, and 39 have been amended.
Claims 12, 14-16, 28-32, and 39 are pending and are under examination.

2. Upon reconsideration, and in view of Applicant's amendment and remarks, all of the previous grounds of rejection are withdrawn.

3. The following are new grounds of rejection.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 14-16, 28-32, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The claims are incomplete for omitting essential steps. While all of the technical details need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The instant claims are drawn to a method for identifying an agent that inhibits T lymphocyte development comprising step (a), assaying IP3KB in the present of a test agent. Step (b) of the method recites identifying an agent that inhibits a cellular level or kinase activity of IP3KB. However, it is unclear how the agent can be identified in step (b) in the absence of performing an assay for kinase activity of IP3KB, or assaying for the cellular level of IP3KB polypeptide or IP3KB gene expression. The claims broadly recite "assaying IP3KB", which might encompass any type of assay, for example assaying the molecular weight of IP3KB, assaying the mobility of IP3KB, assaying the purity of an IP3KB preparation, or assaying the crystal structure of IP3KB. However, it would not be possible to perform step (b) of the method (i.e. identifying an agent that inhibits a cellular level or kinase activity of IP3KB) in the absence of the step of actually performing an assay for said kinase activity or cellular level. Therefore, the lack of a method step for assaying for the kinase activity of IP3KB, or for the level of IP3KB polypeptide/gene expression product in a

cell, is an omission that renders the claims incomplete.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method comprising testing an agent for ability to inhibit T lymphocyte development "in vivo".

Applicant indicates that support for the new limitations of claim 39 can be found on page 21 of the specification. A review of the specification fails to reveal support for the new limitations.

At page 21, the specification discloses that other than using an in vitro system, the modulating activity on T cell development is examined using an animal harboring an IP3KB, including animals harboring an endogenous IP3KB or transgenic mice containing human IP3KB. However, testing an agent in an animal harboring an IP3KB, as disclosed by the specification, has a narrower scope than the instant claims which recite testing said agent "in vivo". For example, the claims might encompass testing the agent in a transgenic plant. Furthermore, the specification does not define the term "animal", but provides examples such as using thymi from mice which have been treated with the agent in-vivo. Thus, it appears that the specification only contemplates testing the agents in non-human animals by removing the thymus after administering the test agent. In support of this it is noted that the term "animal" can be interpreted to mean lower animals, as distinguished from humans (see Medline Medical dictionary definition 2).

Thus, the disclosure by the specification of testing the agent in an "animal" harboring an IP3KB does not appear to encompass testing said agent in humans, as is encompassed by the instant claims which recite testing said agent "in vivo".

6. Claims 12, 14-16, 28-32, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method comprising assaying IP3KB kinase activity in the presence of a test agent, or assaying the level of IP3KB polypeptide or IP3KB gene expression in a cell in the presence of a test agent, followed by identifying one or more agents that inhibits the kinase activity of IP3KB, or inhibits the cellular level of IP3KB polypeptide or IP3KB gene expression,

does not reasonably provide enablement for:

a method comprising assaying IP3KB in the presence of a test agent, followed by identifying one or more agents that inhibits a cellular level or kinase activity of IP3KB.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, *in re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

"The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the

invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)" The MPEP further states that physiological activity can be considered inherently unpredictable.

The instant specification does not enable the method as broadly claimed, since critical or essential steps to the practice of the invention are not included in the claims. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant claims are drawn to a method for identifying an agent that inhibits T lymphocyte development comprising step (a), assaying IP3KB in the present of a test agent. Step (b) of the method recites identifying an agent that inhibits a cellular level or kinase activity of IP3KB. Various methods of assaying for kinase activity of IP3KB are known, including both cell based and cell-free assays (see Woodring et al. and da Silva et al., both of record). Additionally, methods of assaying for the cellular level of IP3KB polypeptide or gene expression are known (see Vanweyenberg et al. and Woodring et al., both of record). However, the instant claims do not recite a step of assaying for kinase activity of IP3KB in the presence of a test agent, or assaying for the cellular level of IP3KB polypeptide or gene expression. Rather, the claims broadly recite "assaying IP3KB". This might encompass any type of assay, for example assaying the molecular weight of IP3KB, assaying the mobility of IP3KB, assaying the purity of an IP3KB preparation, or assaying the crystal structure of IP3KB. However, the specification does not enable performing step (b) of the method (i.e. identifying an agent that inhibits a cellular level or kinase activity of IP3KB) in the absence of a claim limitation reciting the step of performing an assay for said kinase activity or cellular level.

The specification discloses screening assays for identifying agents that inhibit T lymphocyte development. The screening assays comprise assaying IP3KB kinase activity in the presence of a test agent in order to identify a test agent that inhibits kinase activity of IP3KB. The specification further discloses a screening assay comprising assaying the level of IP3KB polypeptide or IP3KB gene expression in a cell in the presence of a test agent in order to identify an agent that inhibits the cellular level of IP3KB gene or IP3KB polypeptide. However, the specification does disclose any other type of "IP3KB assay" that can be used to identify an agent that inhibits the cellular level or kinase activity of IP3KB. Thus, the claims are missing a feature which is taught as critical in the specification (i.e. a method step involving assaying or measuring IP3KB kinase activity, or a method step involving

assaying or measuring the level of IP3KB gene expression, or IP3KB polypeptide in a cell). Accordingly, the method as broadly claimed must be considered highly unpredictable. Given said unpredictability, the method of the instant claims must be considered to require undue experimentation.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 6am - 2pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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